REMARKS

Applicants submit this amendment and response to the Examiner's Final Office Action dated December 3, 2010. The Office Action has been carefully reviewed and the following remarks are made in response thereto. Claims 54-71 are cancelled. Claims 72-85 are new. Support for the amendments can be found throughout the specification. No new matter has been added.

Summary of the Office Action

1. Applicants' previous arguments were deemed partially persuasive. Rejections and objections not reiterated from any previous Office Actions were withdrawn. (Office Action at 2).

2. Claims 54 and 56-69 were rejected for allegedly failing to comply with the enablement requirement. (Office Action at 2-6).

3. Claims 62-64 were rejected as allegedly lacking written description, only "insofar as it pertains to sterols from soya glycines or oxidized soya glycines." (Office Action at 6, last paragraph).

4. No claims were allowed.

5. Applicants reiterate that the Examiner previously indicated in the Office Action dated July 6, 2009 that claim 69 was allowed and that claims 56, 57, 60, 64, and 65 were objected to as being dependent on a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to the Office Action

1. **Rejection of Claims 62-64: Written Description – 35 U.S.C. §112, first paragraph.**

Claims 62-64 were rejected as allegedly failing to comply with the written description requirement, only "insofar as it pertains to sterols from soya glycines or oxidized soya glycines." (Office Action at 6, last paragraph). Without acquiescing to the rejection, claims 62-64 are cancelled. None of the new claims recite sterols from soya glycines or oxidized soya glycines. Thus, the rejections are moot. Applicants expressly reserve the right to claim sterols from soya glycines or oxidized soya glycines in a continuing application.

2. Rejection of Claims 54 and 56-69: Enablement – 35 U.S.C. §112, first paragraph.

Claims 54 and 56-69 were rejected as allegedly failing to comply with the enablement requirement.

The Examiner acknowledged that "it is known how to make the steroidal aromatase inhibitors listing on page 9-11." (Office Action at sentence bridging pages 3-4). The Examiner further stated that "the specification lacks enablement for making aromatase inhibitors **from soya glycines or oxidized soya glycines**." (*Id.* at 4) Without acquiescing to the rejection, the claims, as amended herein, do not recite aromatase inhibitors **from soya glycines**, so this aspect of the rejection is moot. Applicants expressly reserve the right to claim sterols from soya glycines or oxidized soya glycines in a continuing application.

The Examiner further alleges that "there is no correlation shown by the specification that inhibition of aromatase is the cause of the therapeutic effect and the prior art shows unpredictability that aromatase inhibition will augment the amount of collagen present in the skin for the claimed methods." (Office Action at page 5). As shown in detail below, the specification unquestionably correlates inhibition of aromatase with therapeutic effects.

The original specification is replete with express references to collagen deficiencies and treatments that increase collagen content. For example, page 7, lines 4-11 discloses: "It was surprisingly found that said substance(s) or the composition containing this (these) substance(s) exhibit as a consequence of their action a positive influence on the collagen, particularly on the content of the collagen fibres within the collagen containing body region such as the skin, thereby rendering these body region more tight or firm. By means of biopsies it was

found that the proportion of collagen fibres increased." Page 21, lines 13-20 discloses that a "characteristic of the skin of pregnancy strias is a decrease of collagen content." Page 22, line 34 – page 23, line 12 is directed to treatment of "collagen deficiency conditions," and discloses that according to the present invention, "the content of collagen fibres of the skin is increased." Moroever, page 23 at lines 4-12 expressly teaches that "contrary to the official scholarship opinion," but as disclosed by the application "being founded by experimental studies," according to the instant disclosure and invention "the content of collagen fibers of the skin is increased" by using aromatase inhibitors. Page 23, lines 14-20 is directed to treating wrinkles in the face and open-necked regions, pregnancy strias or stretched strias at the lower abdomen, the thighs and the buttock and expressly discloses "to increase the percentage of collagen fibers of the skin." Page 24, lines 28-33 discloses "an increase of collagen fibers ... and accordingly to an increase of the thickness and tightness of the skin." Page 32, lines 29-30 discloses "sun-bathing decreases the collagen content of the skin."

Moreover, the examples and accompanying figures disclose actual reductions to practice. The specification expressly discloses that wrinkles and strias are "well visible especially in the case of dark skin color." Page 23, lines 19-20. Examples 1.1 and 1.2 are directed to a 60-year-old man and a 50-year old woman having "strong wrinkle formation[s]" in their eye regions. Example 1.1 discloses a ten week treatment resulting in "an almost disappearance of the wrinkles." Example 1.2 discloses an eight week treatment resulting in "strong smoothening of the upper skin in the region of the wrinkle formation around the yes" and after sixteen weeks the "wrinkles have disappeared.

Similarly, example 2 discloses a subject having "strong formation of wrinkles in the lower region of the face, especially in the region of the cheek and chin." Example 2 discloses a six week treatment resulting in noticeable smoothing of wrinkles and a twelve week treatment resulting in only slight visible wrinkles.

Example 3 discloses a woman with "wrinkles in the outer skin layer of the upper arms." Examples 3 discloses a successful 16 week treatment resulting in the wrinkles becoming "practically invisible." Figures 1 and 2 discloses biopsies before and after this treatment.

Example 4.1 discloses a mother of two children having "strong pregnancy strias in the region of the abdomen." Example 4.2 discloses a woman having "stretched strias in the region of the thighs and buttock." Moreover, page 22 line 34 of the original specification discloses "treating collagen deficiency conditions of the outer skin." (emphasis added). Example 4.1 discloses a treatment eliminating pregnancy strias. Example 4.2 discloses a successful treatment, making the strias become "practically not visible." Figures 3 and 4 show the subject before and after this treatment.

Example 5 discloses a successful treatment for strong overstretching and pain in the ligaments and tendons of both knees using 4-hydoxy-androstendione. A normal ligament is made up primarily by collagen, and a small amount of fibroblast cells. Similarly, tendons are mostly composed of parallel arrays of collagen fibers.After several weeks, there was a remarkable reduction in pain, and a feeling of stabilization of the joints of the knees.

The Examiner admits that the skill in the art is high, generally that of a medical doctor or Ph.D. biochemist. (Previous Office Action at page 5). Administration of the claimed substances is not particularly difficult to a person having ordinary skill in the art. As such, the claimed invention can be practiced with routine experimentation. Quantity of examples is only one factor that must be considered before reaching the final conclusion that undue experimentation would be required. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404.

As shown above, the specification provides a detailed listing of steroidal inhibitors, all of which the Examiner acknowledges can be made by methods known in the art. Further, the examples provide actual reduction to practice of the steroidal soya glycines and Formestan. As long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. 112 is satisfied. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Most importantly, in this case, contrary to the Examiner's position that "there is no correlation shown by the specification that inhibition of aromatase is the cause of the therapeutic effect," the specification clearly discloses such a correlation. (*See e.g.*, specification at page 7, lines 4-11; page 21, lines 13-20; page 22, line 34 – page 23, line 12; page 23, lines 14-20; page 24, lines 28-33). What is more, steroidal aromatase inhibitors share a

common sterane core which enables them to effectively penetrate the dermis in order to reach the underlying collagen.

Failure to disclose other methods by which the claimed invention may be made does not render a claim invalid under 35 U.S.C. 112. *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1533, 3 USPQ2d 1737, 1743 (Fed. Cir.), *cert. denied*, 484 U.S. 954 (1987). Not everything necessary to practice the invention need be disclosed. In fact, what is well-known is best omitted. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991). All that is necessary is that one skilled in the art be able to practice the claimed invention, given the level of knowledge and skill in the art. If a statement of utility in the specification contains within it a connotation of how to use, and/or the art recognizes that standard modes of administration are known and contemplated, 35 U.S.C. 112 is satisfied. *In re Johnson*, 282 F.2d 370, 373, 127 USPQ 216, 219 (CCPA 1960); *In re Hitchings*, 342 F.2d 80, 87, 144 USPQ 637, 643 (CCPA 1965). For example, it is not necessary to specify the dosage or method of use if it is known to one skilled in the art that such information could be obtained without undue experimentation. If one skilled in the art, based on knowledge of compounds having similar physiological or biological activity, would be able to discern an appropriate dosage or method of use without undue experimentation, this would be sufficient to satisfy 35 U.S.C. 112, first paragraph. MPEP §2164.01(c).

In sum, since the claims, as amended, do not recite aromatase inhibitors **from soya glycines**; since the claimed steroidal aromatase inhibitors share a common sterane core which enables them to effectively penetrate the dermis in order to reach the underlying collagen; since the claimed steroidal aromatase inhibitors can be made by methods known in the art; and since the specification discloses a correlation between application of the claimed steroidal aromatase inhibitors and the claimed effect, the enablement rejections are moot or otherwise accommodated. Withdrawal of the remaining rejections and allowance of the new claims is respectfully requested.

CONCLUSION

Applicant believes that the above-reference application is in condition for allowance. Reconsideration and withdrawal of the outstanding rejections and objections and early notice of allowance to that effect is respectfully requested.

EXCEPT for issue fees payable under 37 C.F.R. § 1.18, the Director is hereby authorized by this paper to charge any additional fees during the entire pendency of this application, including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account No. 13-3250, reference No. 38891.00100US. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 C.F. R. § 1.136(a)(3).

Respectfully submitted,

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